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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,734	05/01/2007	Geila Rozen	85189-9500	3116

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

NOTIFICATION DATE	DELIVERY MODE
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08/30/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/591,734	Applicant(s) ROZEN ET AL.	
	Examiner DEBORAH D. CARR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9,12-22, 24-31, 34-44, 46--52 and 61-65 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9,12-18,21,22,24-28,31,34-40,43,44,46-50,61,63 and 65 is/are rejected.
- 7) ☒ Claim(s) 19,20,29,30,41,42,51,52 and 64 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see pages 12-14, filed 14 June 2010, with respect to the rejection(s) of claim(s) 9, 12-18, 21-22, 27-28, 31, 34-40, 43-44, 49-50, 61, 64-65 under 35 USC §102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Klang et al.

(New) Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9, 12-18, 21-22, 24-28, 31, 34-40, 43-44, 46-50, 61, 63, 65 rejected under 35 U.S.C. 103(a) as being unpatentable over EP 271,909 or EP 265,699 or EP 965,578 in view of Klang et al.

EP'909 teaches structured triglycerides that can be used in parenteral nutrition emulsions wherein the fatty acid residues are selected from C₆₋₁₂, C₁₄₋₁₈, & C₁₈₋₂₂ fatty acids. (See page 3, col.2 & page 4, col. 3); the fatty acid residues are present in the amounts which read on claims 13-18 (see page 4, col. 3).

EP'699 teaches structured triglycerides that can be used in parenteral nutrition emulsions wherein the fatty acid residues are selected from C₆₋₁₂, C₁₄₋₁₈, & C₁₈₋₂₂ fatty

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acids. (See pages 1-2, Table 1, and the claims) and the 2 position of the triglyceride contains C₈₋₂ fatty acid residues.

EP'578 teaches structured triglycerides that can be used in parenteral nutrition emulsions wherein the fatty acid residues are selected from C₆₋₁₂, C₁₄₋₁₈, & C₁₈₋₂₂ fatty acids. (See page 3, formula II; page 5, formula II; page 7, section [0048]); the structured triglycerides are present in the amounts which read on claims 21-22 (see page 7, section [0047]); the composition contains other components which read on claims 27-28 (section [0046]).

Theses references differ from the claims by not stating specifically that the emulsion has a droplet size of less than about 1 μm . However it would have been obvious to one of ordinary skill in the art at the time the invention was made to reduce the droplet size of the emulsion below 1 μm .

Klang et al. disclose the following regarding reducing the droplet size of the emulsion below 1 μm :

Intravenous emulsions, like all parenteral products, are required to meet pharmacopoeial requirements (Benita and Levy, 1993). The emulsions must be sterile, isotonic, non-pyrogenic, non-toxic, biodegradable and stable, both physically and chemically. Furthermore, the particle size of the droplets needs to be below one micron, and generally ranges between 100–500 nm. With larger droplet size, potential oil embolism may occur (Wretlind, 1964; Levene *et al.*, 1980).

Therefore, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded

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predictable results to one of ordinary skill in the art at the time of the invention. KSR International Co. v. Teleflex Inc., 550 U.S. ___, 82 USPQ2d 1385 (U.S. 2007).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

4. Claims 19-20, 29-30, 41-42, 51-52, 64 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH D. CARR whose telephone number is (571)272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel M. Sullivan can be reached on 571-272-0779. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah D Carr/
Primary Examiner
Art Unit 1621

Ddc